REMARKS

Claims 32, 38, 40-45, 48, 52, 54, 55, 58 and 79-88 are pending. The Office alleges that the claims are directed to three distinct and independent inventions as follows:

Group I : Claims 32 and 38, directed to a method of screening for anticancer activity of a drug candidate comprising: contacting a cell that expresses a cancer associated (CA) gene encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 with an anticancer drug candidate; and monitoring an effect of the anticancer drug candidate on expression of the CA polynucleotide, wherein an anticancer drug candidate which reduces expression of the nucleic acid is identified as a drug having anticancer activity and wherein said nucleotide sequence at least 95% identical to SEQ ID NO: 41 encodes a polypeptide with signaling activity;

Group II : Claims 40, 41 and 79-94 (when detection of polypeptide is elected), directed to a method for detecting cancer associated with expression of a polypeptide encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 in a patient sample, comprising: comparing a level of expression of the polypeptide in the patient sample with a level of expression of the polypeptide in a normal sample, wherein an altered level of expression of the polypeptide in the patient sample relative to the level of polypeptide expression in the normal sample is indicative of the presence of kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer in the patient sample, wherein said nucleotide sequence at least 95% identical to SEQ ID NO: 41 encodes a polypeptide with signaling activity;

Group III : Claim 42, directed to a method for detecting cancer associated with expression of a polypeptide encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 in a patient sample, comprising: comparing a level of signaling activity of the polypeptide in the test sample with a level of signaling activity of the polypeptide in a normal sample, wherein an altered level of signaling activity of the polypeptide in the patient sample relative to the level of polypeptide signaling activity in the normal sample is indicative of the presence of kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer in the patient

sample, wherein said nucleotide sequence at least 95% identical to SEQ ID NO: 41 encodes a polypeptide with signaling activity;

Group IV : Claim 43, directed to a method for detecting cancer associated with the presence of an antibody in a patient sample, wherein the antibody specifically binds a polypeptide having an amino acid sequence at least 95% identical to SEQ ID NO: 42, or immunogenic fragment thereof, the method comprising: comparing a level of said antibody in the patient sample with a level of said antibody in a control sample, wherein an altered level of antibody in said patient sample relative to the level of antibody in the control sample is indicative of the presence of kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer in the patient sample, wherein the polypeptide has signaling activity;.

Group V : Claims 44, 45 and 48, directed to a method for screening for a bioactive agent capable of modulating the activity of a CA protein (CAP), wherein said CAP is encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 comprising:

a) contacting a cell that expresses a cancer associated (CA) gene encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 or fragment thereof with a candidate bioactive agent; and

b) comparing the effect of the candidate bioactive agent on expression of the CA polynucleotide in the presence of the candidate agent to expression of the CA polynucleotide in the absence of the candidate agent; wherein a candidate bioactive agent which modulates the expression of the CA gene is identified as a bioactive agent capable of modulating the activity of a CAP and wherein said nucleotide sequence at least 95% identical to SEQ ID NO: 41 encodes a polypeptide with signaling activity;

Group VI : Claims 52 and 79-94 (with respect to detection of the level of mRNA), directed to a method for diagnosing kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer comprising: comparing a level of nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41 in a patient sample comprising human prostate, lung, bladder, breast, stomach or colon tissue to a level of nucleic acid in a control sample, said nucleotide sequence at least 95% identical to SEQ ID NO: 41 encoding a polypeptide with

signaling activity; wherein an increase of at least 50% from the level of nucleic acid in the patient sample compared to the level of the nucleic acid in the control indicates that the patient has kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer;

Group VII : Claims 54, 55 and 58, directed to a method for treating cancer comprising administering to a patient an inhibitor of a CA protein (CAP), wherein said CAP is encoded by a nucleic acid comprising a nucleotide sequence at least 95% identical to SEQ ID NO: 41; and

Group VIII : Claims 95-98, directed to a method of diagnosing kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer comprising:

a) determining the level of a nucleic acid that hybridizes under highly stringent conditions to a nucleic acid comprising a nucleotide sequence of SEQ ID NO:41 in a patient sample•, wherein hybridization is performed at 50°C to 60°C in 5 X SSC (9 mM NaC1/0.9 mM sodium citrate); and

b) comparing said level of nucleic acid in (a) to a level of the nucleic acid in a second sample, said second sample comprising a negative control; wherein an increase of at least 50% between the level of the nucleic acid in (a) and the level of the nucleic acid in the second sample indicates that the patient has kidney cancer, colon cancer, prostate cancer, breast cancer or stomach cancer.

The Office Action is requiring restriction to a single disclosed invention under 35 U.S.C. §121. Applicant traverses the Restriction Requirement for the reasons stated below. Nevertheless, in order to be responsive to the Office Action, Applicant elects the invention of Group VI, claim 52 and 79-94, directed to a method for diagnosing kidney, colon, prostate, breast or stomach cancer comprising comparing the level of SEQ ID NO:41 in a patient sample compared to a normal sample. Applicant reserves the right to pursue prosecution of the non-elected claims in a later filed application claiming the benefit of priority of the above-identified Application.

Applicants submit that, while the claims of Group VI are patentably distinct from the claims of Groups I-V, VII and VIII, a thorough search of the elected claims of Group VI will

include art relevant to the claims of the remaining Groups. In particular, a thorough search of SEQ ID NO:41 recited in Group VI, directed to a method for diagnosing kidney, colon, prostate, breast or stomach cancer comprising employing SEQ ID NO:41, will encompass the methods of Groups I-V, VII and VIII because all Groups of claims are directed to a diagnostic or detection method using SEQ ID NO:41.

For example, Group I, claims 32 and 38, is directed to a method of screening for anticancer activity of a drug candidate using SEQ ID NO:41. Group II, claims 40, 41 and 79-94, is directed to a method for detecting cancer using SEQ ID NO: 41. Group III, claim 42, is directed to a method for detecting cancer using SEQ ID NO:41. Group IV, claim 43, is directed to a method for detecting cancer using the polypeptide encoded by SEQ ID NO:41. Group V, claims 44, 45 and 48, is directed to a method for screening for a bioactive agent using SEQ ID NO:41. Group VII, claims 54, 55 and 58, is directed to a method for treating cancer by administering an inhibitor of SEQ ID NO:41. While Group VIII, claims 95-98, is directed to a method of diagnosing kidney, colon, prostate, breast or stomach cancer using SEQ ID NO:41 under specified hybridization conditions. Accordingly, the joint examination of claims 32, 38, 40-45, 48, 52, 54, 55, 58 and 79-88 will not result in a serious burden on the Examiner and rejoinder of all Groups is respectfully is requested.

The Office Action also is requiring a species election under 35 U.S.C. §121 for the inventions of Group VI. Election is required of a single species corresponding an particular species of cancer selected from kidney, colon, prostate, breast or stomach.

Applicant respectfully traverses the election of species because a search of each recited cancer would not be unduly burdensome on the Examiner, particularly in light of the search likely requiring a nucleic acid sequence search. Hence, a thorough search of the nucleic acid would necessarily will revel any cancers it is associated with. Nevertheless, Applicant elects the species directed to kidney, claims 52 and 79. Upon allowance of a generic claim, Applicant requests consideration of the additional species for prosecution on the merits in this application.

CONCLUSION

In view of the remarks submitted herein, Applicant respectfully requests that the invention of Group VI claims be examined. In addition, Applicant requests the that the species directed to kidney cancer be initially prosecuted on the merits. Applicant appreciates the Examiner's reconsideration of the Restriction and Election of Species Requirements. The Examiner is invited to call the undersigned attorney if there are any questions regarding this application.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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